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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO |
|--------------------|-------------|-----------------------|--------------------|

EXAMINER

MM. 27/12/99

HELEN GREEN  
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BOSTON MA 02111

ART UNIT INTL PAPER NUMBER

29

DATE MAILED: 16/23

12/28/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on \_\_\_\_\_  
 This action is FINAL.  
 Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire ONE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1 - 24, 28-30, 35-38, 40, and 42-70 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) \_\_\_\_\_ is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims 1-24, 28-30, 35-38, 40, and 42-70 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
The proposed drawing correction, filed on \_\_\_\_\_ is \_\_\_\_\_ approved \_\_\_\_\_ disapproved.  
The specification is objected to by the Examiner.  
The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None  of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

BEST AVAILABLE COPY

- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

## DETAILED ACTION

1. The examiner and the location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.
2. Claims 1-24, 28-30, 35-38, 40 and 42-70 are pending.  
Claims 25-27, 31-34, 39 and 41 have been canceled.
3. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods and products. The method and agents/products rely upon sialyl Lewis x, sialyl Lewis a, P-selectin, PSGL-1, 160 kD monospecific P-selectin ligand, P-selectin mimic or P-selectin mimic or antibodies thereto which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species. Further, it is noted that pages 8-12 of the instant specification discloses a number of patentably distinct agents, which may be subject to further restriction and/or species election. Applicant is invited to clearly elect a single Group as it reads on a particular therapeutic agent and to provide an appropriate claim that reads on the elected invention. The Groups set forth below appear to read on the claims as currently recited, but may be subject to further Restriction and/or species election depending on the claimed recitation.
4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-5, 7-12, 19, 20, 23, 28-30, 35-37, 40-45, 53, 55-57, , drawn to methods of treating or inhibiting atherosclerosis wherein the agent is sialyl Lewis x classified in Class 514, subclass 23.
  - II. Claims 1-5, 7-12, 19, 20, 23, 28-30, 35-37, 40-45, 55-57, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is sialyl Lewis a, classified in Class 514, subclass 23.
  - III. Claims 1-4, 6-14, 17, 21, 22, 24, 48-51, 55- 59, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is P-selectin, classified in Class 514, subclass 8.
  - IV. Claims 1-4, 6-14, 17, 21,22, 24, 48, 54-59, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is PSGL-1, classified in Class 514, subclass 2.
  - V. Claims 1-4, 6-14, 17, 21, 22, 24, 48, 54-59, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is a 160 kD P-selectin ligand, classified in Class 514, subclass 2.
  - VI. Claims 1-5, 7-12, 13, 14, 17, 21, 22, 24, 55-57, 70, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is a P-selectin mimic, classified in Class 514, subclass 2.

VII. Claims 1-5, 7-12, 13, 14, 17, 21, 22, 24, 55-57, 70, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is P-selectin ligand mimic, classified in Class 514, subclass 2.

VIII. Claims 1-4, 7-12, 18, 25, 26, 55-57, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is derived from snake venom, classified in Class 424, subclass 542.

IX. Claims 1-4, 7-12, 18, , 55-57, drawn to methods of treating or inhibiting atherosclerosis wherein the agent is derived from a plant extract, classified in Class 424, subclass 195.1

X. Claims 1-4, 7-12, 28-30, 35-37 drawn to methods of treating or inhibiting atherosclerosis wherein the agent is P-selectin-specific antibody, classified in Class 514, subclass 8.

XI. Claims 1-4, 7-12, 28-30, 35-37 drawn to methods of treating or inhibiting atherosclerosis wherein the agent is PSGL-1-specific antibody, classified in Class 514, subclass 2.

XII. Claims 1-4, 7-12, 28-30, 35-37 drawn to methods of treating or inhibiting atherosclerosis wherein the agent is a 160 kD P-selectin ligand-specific antibody, classified in Class 514, subclass 2.

XIII. Claim 46, drawn to methods of treating or inhibiting atherosclerosis with an agent that inhibit P-selectin-P-selectin ligand and agent that inhibits L-selectin and L-selectin ligand, classified in Class 514, subclass 8.

It is noted that if applicant elects this Group, this Group will be subject to further restriction, given the number of patentably distinct reagents for an agent that inhibits P-selectin:P-selectin ligand and agent that inhibits L-selectin:L-selectin ligand.

XIV. Claim 47 and 60-67, drawn to methods of treating or inhibiting atherosclerosis with an agent that inhibit P-selectin-P-selectin ligand and agent that inhibits E-selectin and E-selectin ligand, classified in Class 514, subclass 8.

It is noted that if applicant elects this Group, this Group will be subject to further restriction, given the number of patentably distinct reagents for an agent that inhibits P-selectin:P-selectin ligand and agent that inhibits E-selectin:E-selectin ligand.

XV. Claim 68-69, drawn to chimeric molecules comprising a P-selectin ligand and another molecule, classified in Class 424, subclass 185.1.

It is note that if applicant elects this Group, this Group will be subject to further restriction, given the number of patentably distinct reagents for a P-selectin ligand and another molecule.

XVI. Claims 38, drawn to a therapeutic agent which is sialyl Lewis x, classified in Class 514, subclass 23.

XVII. Claim 38, drawn a therapeutic agent which is sialyl Lewis a, classified in Class 514, subclass 23.

XVIII. Claim 38, drawn to a therapeutic agent which is P-selectin, classified in Class 514, subclass 8.

XIX. Claim 38, drawn to a therapeutic agent which is PSGL-1, classified in Class 514, subclass 2.

XX. Claim 38, drawn to a therapeutic agent which is a 160 kD P-selectin ligand, classified in Class 514, subclass 2.

XXI. Claim 38, drawn to a therapeutic agent which is a P-selectin mimic, classified in Class 514, subclass 2.

XXII. Claim 38, drawn to a therapeutic agent which is a P-selectin ligand mimic, classified in Class 514, subclass 2.

XXIII. Claim 38, drawn to a therapeutic agent which is derived from snake venom, classified in Class 424, subclass 542.

XXIV. Claim 38, drawn to a therapeutic agent which is derived from a plant extract, classified in Class 424, subclass 195.1.

5. Inventions XV-XXIV and I-XIV are related as products and processes of use, respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the products as claimed can be used in a materially different process such as affinity purification, as immunogens or various detection of bioassays.

Alternatively, there are other known cardiovascular reagents and procedures which are employed to inhibit or treat atherosclerosis.

6. Inventions I-XIV are different methods, which require patentably distinct ingredients. Therefore, they are patentably distinct.

7. Inventions XV-XXIV are different products. The various therapeutic agents are distinct because their structures and modes of action are different, which require non-coextensive searches. These agents are different with respect to biochemical properties; including primary, secondary and tertiary structure. Therefore, they are patentably distinct.

8. Because these inventions are distinct for the reasons given above and the search required for any Group from Groups I-XXIV is not required for any other group from Groups I-XXIV and Groups I-XXIV have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gabel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

*Phillip Gabel*  
Phillip Gabel, PhD.  
Primary Examiner  
Technology Center 1600  
October 9, 2001